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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/413,110	10/06/1999	EVAN C. UNGER	UNGR-1580	1596

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/413,110

Applicant(s)

UNGER, EVAN C.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 116-185 is/are pending in the application.
- 4a) Of the above claim(s) ~~116-132-137, 142-145, 152-159, 161-163, 167 and 175~~ ¹⁷⁷ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 116-131, 138-141, 146-151, 160, 164, 168-174, and 178-185 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on March 14, 2003 has been entered. Claims 116-185 are pending. Claims 132-137, 142-145, 152-159, 161-163, 167, 175-177 are withdrawn as they are directed to nonelected species. Claims 116-131, 138-141, 146-151, 160, 164, 168-174, 178-185 are under consideration.

Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment.

Double Patenting

Claims 116-131, 138-141, 146-151, 160,164, 168-174, and 178-185 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over patented claims 1-96 of U.S. Patent No. 6,443,898 B1, and claims 1-15 of US Patent 6,416,740 B1, and claims 1-63 of US Patent 6,403,056 for the reasons of record. Applicant's amendment has not modified the scope of this rejection. The patented claims and the pending claims are obvious variants of each other because the method steps utilizes similar therapeutic composition and are manipulatively the same.

Claims 116-131, 138-141, 146-151, 160,164, 168-174, and 178-185 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/218,660, 09/813,484, 10/055,772 for the same reasons as set fort above.

Claim Rejections - 35 USC § 102

Claims 116-131, 138-140, 160,164-166, 168-174, and 178-184 stand rejected under 35 U.S.C. 102(b) as being anticipated by Siegel US Patent 5,695,460.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that Siegel fails to set forth the element that the gaseous vesicles or acoustically active compositions are administered to a patient by continuous infusion. Applicant further adds that Siegel does not deliver a thrombolytic agent to a selected tissue. (Amendment, p. 5).

In response to the first argument Examiner replies that "continuous infusion" as described in page 13 of the instant specification mean to the rate of delivery to a patient into a vessel lumen or body cavity, over a period of time, by needle, catheter or other means. Siegel meets this element. Attention is drawn to figure 1 of Siegel and the description of element 12 on col 4, lines 15-26. Accordingly, Siegel administers the drug combination through a catheter or needle over a period of time. Thus, Siegel discloses continuous infusion within the meaning of the instant claims.

With respect to Applicant's second argument, Examiner replies that Siegel expressly states methods of improving or treating cardiovascular obstruction. Thus, delivery of his combination is directed to cardiovascular tissues. (see col 3, lines 20-33, examples 1-3). Under the principle of inherency, as argued in the previous Office Action at page 6, Siegel uses similar methods steps and similar composition, therefore, the process steps are essentially the same as those instantly claimed.

Finally, Applicant's position over the terms "sufficient" or capable is noted, however, Applicant has not provided any evidence showing that Siegel's ultrasonic energy is not sufficient to meet the endpoints instantly claimed. In fact, Siegel employs about the same frequencies as the instant claim 185 (see col 5, lines 29-38, col 7, lines 45-56). Thus Siegel applies sufficient amount of energy to cause delivery of bioactive agents.

Applicant argues that Siegel teaches away from the instant frequencies. In response, Examiner states that Siegel is an anticipatory prior art and thus the rejection is an anticipation type, and not an obviousness rejection. Accordingly, so long as Siegel discloses the use of instantly claimed frequencies, the method step is anticipated. Siegel employs such frequencies as claimed namely 85, 105, and 243 kHz. Thus, Siegel anticipates this limitation.

Claims 116-131, 138-141, 146-151, 160, 164, 168-174, and 178-185 are rejected under 35 U.S.C. 102(e) as being anticipated by Klaveness et al Patent 6,331,289.

Applicant argues that Klaveness is directed to vesicle compositions wherein vesicles contain the therapeutically active compositions. However, Klaveness also discloses compositions that are attached to the targeting ligands or compositions wherein the targeting ligand can be the therapeutic agent. Such ligands are not encapsulated rather exist outside the vesicle. (see claims 17-20, examples 16-18). Applicant's claims do not exclude such compositions. Therefore, Klaveness's teachings are anticipatory and the claims are properly rejected.

Claims 116-131, 138-141, 146-151, 160,164, 168-174, and 178-185 are rejected under 35 U.S.C. 102(e) as being anticipated by Schneider US Patent 6,258,378 for the similar reasons as described for Klaveness.

Claim Rejections - 35 USC § 103

Claims 141, 146-151, 185 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel et al US Patent 5,695,460.

Applicant argues that the instant methods are directed to delivering a bioactive agent to selected tissues, and Siegel's methods does not provide delivery to selected tissue.

In reply Examiner states that as discussed above, Siegel clearly teaches the method steps of the instant claims, accordingly absence of showing unexpected results, modifying the rate of infusion and the ultrasound frequency would have been achieved by routine experimentation.

Claims 116-131, 138-141, 146-151, 160,164-166, 168-174, and 178-184 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Porter US Patent 5,648,098 in view of Siegel et al US Patent 5,695,460 for the reasons of record.

Applicant argues that neither of the cited references is directed to delivery of a bioactive agent and that the element of selected tissue is not taught in neither references. In response Examiner states that as reasoned in previous Office Action, Porter and Siegel suggests the use of a ultrasonic gaseous contrast agents with a therapeutic agent to improve the therapeutic end result. Selecting the site of interest would have been well within the level of one of ordinary skill in the art. Further,

Applicant has not provided any evidence showing the contrary or setting forth patentable differences in operation of a the Siegel's method of delivery to cardiovascular clot and cardiovascular tissue. Accordingly, the rejection is maintained.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

SS
June 2, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200